Purdue Pharma L.P. et al v. Acura Pharmaceuticals Inc. et al Doc. 48

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., and THE P.F. LABORATORIES, INC., Plaintiffs, v. ACURA PHARMACEUTICALS, INC., EGALET CORPORATION, and EGALET US, INC., Defendants.	Civil Action No. 15-292-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of early claim construction of one term in U.S. Patent No. 8,389,007 ("the '007 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 39). The Court heard oral argument on November 24, 2015.

I. BACKGROUND

The '007 patent is directed to an immediate release pharmaceutical tablet, containing the active ingredient oxycodone hydrochloride, that is resistant to various forms of abuse. ('007 patent, col. 2, ll. 13–36; *id.* claims 1, 12, 13). Independent claim 1 is representative and reads:

> 1. A tamper-resistant immediate release pharmaceutical tablet comprising a compressed mixture comprising:
> (a) oxycodone hydrochloride;
> (b) polyethylene oxide in a ratio to oxycodone hydrochloride from about 1:1 to about 40:1 by weight;
> (c) polyvinylpyrrolidone; and
> (d) a surfactant;
> wherein the polyethylene oxide forms a gel upon tampering with the tablet by solvent extraction such that when the tampered tablet is dissolved in about 1 ml to about 5 ml of an aqueous liquid the resultant mixture has a viscosity of at least 10 cP.

(*Id.* claim 1). The specification discloses polyvinylpyrrolidone, the sole term disputed in the current proceeding, as potentially serving as a gelling agent, a disintegrant, or a binder. (*Id.* col. 6, ll. 37–49; *id.* col. 24, ll. 31–32; *id.* col. 25, ll. 6–13).

Defendants manufacture and sell Oxaydo, which they describe as "the first and only approved immediate-release oxycodone product formulated to discourage abuse . . . for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate." (D.I. 1-4 at 1–2). In addition to the active analgesic ingredient oxycodone hydrochloride, Oxaydo contains, among other ingredients, crospovidone, a specific excipient.[1]

[1] The parties agree that excipients are ingredients other than the active ingredient in a pharmaceutical composition that can, among other functions, deter traditional methods of abuse. (D.I. 39 at pp. 4, 16).

(D.I. 1-3 at 16). The crux of the parties' dispute over the term polyvinylpyrrolidone centers on whether crospovidone is encompassed by the claim term.

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim

construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

III. CONSTRUCTION OF THE DISPUTED TERM

A. The '007 Patent

1. "polyvinylpyrrolidone"

   a. *Plaintiffs' proposed construction*: "A polymer of N-vinyl-2-pyrrolidone."

   b. *Defendants' proposed construction*: "A water-soluble synthetic polymer consisting of linear 1-vinyl-2-pyrrolidone groups, the degree of polymerization of which results in polymers of various molecular weights. The term excludes crospovidone."

c. *Court's construction*: "A polymer of N-vinyl-2-pyrrolidone."

The parties do not dispute that both povidone and crospovidone come from the same source monomer: vinylpyrrolidone.[2] (D.I. 39 at pp. 5–6, 24). They also do not dispute that povidone and crospovidone have the same Chemical Abstract Service ("CAS") Registry number and identical chemical formulas.[3] (*Id.* at pp. 6, 40). Moreover, the parties acknowledge notable differences between povidone and crospovidone: povidone is a linear polymer and is water soluble, while crospovidone is cross-linked and is insoluble. (*Id.* at pp. 7, 18). Plaintiffs' position is that the ordinary and customary meaning of polyvinylpyrrolidone is a polymer of N-vinyl-2-pyrrolidone,[4] which would include povidone and crospovidone. (*Id.* at pp. 7–9). Defendants' position, however, is that a POSITA would understand the term polyvinylpyrrolidone to refer only to povidone. (*Id.* at p. 24).

The crux of Plaintiffs' argument is that the ordinary and customary meaning of polyvinylpyrrolidone is "a polymer of N-vinyl-2-pyrrolidone," or, in other words, a polymer of the source monomer vinylpyrrolidone. (D.I. 39 at pp. 4–6). Plaintiffs frame polyvinylpyrrolidone as a broader chemical term, which encompasses both the linear (povidone) and cross-linked polymers (crospovidone) of the same underlying monomer. (*Id.* at pp. 7–9). Plaintiffs also point to several publications that refer to crospovidone as "insoluble polyvinylpyrrolidone," asserting that these publications confirm that crospovidone is a type of

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[2] Polymers are created by the linking together, or polymerization, of underlying molecules, known as source monomers. (D.I. 40-23 at 4). Polymers are commonly named by adding the prefix "poly" to the applicable source monomer. (D.I. 40-24 at p. 10). Neither party disputes this characterization of polymers.

[3] The UNITED STATES PHARMACOPEIA confirms that povidone and crospovidone have identical chemical formulas and CAS Registry numbers. (D.I. 40-33 at 4, 6). CAS Registry numbers are "universally used to provide a unique, unmistakable identifier for chemical substances" and "an unambiguous way to identify a chemical substance or molecular structure when there are many possible systematic, generic, propriety or trivial names." (D.I. 40-32 at 2).

[4] Plaintiffs' construction refers to the source monomer as "N-vinyl-2-pyrrolidone," while Defendants' construction calls it "1-vinyl-2-pyrrolidinone." (D.I. 39 at p. 1). The parties agree that these are merely different ways to refer to the same vinylpyrrolidone monomer. (*Id.* at pp. 5 n.2, 24). Therefore, this difference in the language used to refer to the underlying monomer is not important to the present dispute.

polyvinylpyrrolidone. (*Id.*). Accordingly, Plaintiffs argue that Defendants are improperly importing the limitations of linearity and solubility into their construction, despite the complete lack of a lexicographic definition in the specification or an otherwise clear disavowal by the patentee of the ordinary and customary meaning of the term. (*Id.* at pp. 13–14).

Defendants argue that there are textbooks incorporated by reference in the '007 patent that provide intrinsic evidence that defines polyvinylpyrrolidone as a water-soluble, linear polymer of vinylpyrrolidone, which are characteristics of povidone, but not of crospovidone. (D.I. 39 at pp. 17, 28–29). They therefore argue that this intrinsic evidence provides a controlling ordinary and customary meaning, under *Phillips*, that would exclude crospovidone. (*Id.* at pp. 18–19). Defendants also criticize Plaintiffs for relying on "naming guidelines for polymers in the field of general polymer chemistry," where the POSITA here should not be a chemist, but one "skilled in the art of pharmaceutical formulation." (*Id.* at 18–19, 39–41). Defendants also emphasize "vastly different properties" between povidone and crospovidone—crospovidone's cross-linked structure, insolubility, and lack of a measurable molecular weight—and suggest that the '007 patent's teachings are inconsistent with these properties of crospovidone. (*Id.* at pp. 24–26, 29–31). Defendants also assert that the references describing crospovidone as "cross-linked" or "insoluble" polyvinylpyrrolidone actually support Defendants' position, because every time crospovidone is referred to there is always a modifier. (*Id.* at 20, 36–37). Thus, according to Defendants, the term polyvinylpyrrolidone, standing alone without modifiers, does not include crospovidone.[5] (*Id.*).

At the outset, I conclude that the texts incorporated by reference in the '007 patent do not offer a controlling definition of the term polyvinylpyrrolidone. Defendants rely primarily on

[5] The bulk of Defendants' arguments are supported by the expert declaration of Dr. Arthur Kibbe. (D.I. 40-42).

REMINGTON'S PHARMACEUTICAL SCIENCES (16th ed. 1980) and the American Pharmaceutical Association's HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (1986) for their purported definitions in the intrinsic record. (D.I. 39 at p. 28 (citing D.I. 40-8; D.I. 40-9)). Specifically, Defendants argue that "Remington's 1980 defines polyvinylpyrrolidone as: 'a synthetic polymer consisting of linear 1-vinyl-2-pyrrolidinone groups, the degree of polymerization of which results in polymers of various molecular weights.' The same entry also describes polyvinylpyrrolidone as 'soluble in water . . . .'" (*Id.* (quoting D.I. 40-8 at 4) (alteration in original) (citations omitted)). However, the portion of REMINGTON'S that Defendants cite for this definition is actually an entry for povidone. (D.I. 40-8 at 4). Polyvinylpyrrolidone is only listed as a synonym of povidone in this entry. (*Id.*). The cited portion of the HANDBOOK OF PHARMACEUTICAL EXCIPIENTS that Defendants rely upon for their definition is likewise an entry for povidone, again only listing polyvinylpyrrolidone as a synonym. (D.I. 40-9 at 4).

In their Sur-Reply brief, Defendants concede that their definition comes from entries for povidone, but they essentially argue that these entries still in effect define polyvinylpyrrolidone for various reasons. (D.I. 39 at pp. 58–59). Specifically, they argue that the HANDBOOK states that synonyms are "other names for the excipient," that crospovidone and polyvinylpyrrolidone are not listed as synonyms of one another in these texts, and that cross references in the indices of these texts link polyvinylpyrrolidone with characteristics of povidone. (*Id.*). Plaintiffs offer the declaration of their expert, Dr. Stephen Byrn,[6] who states that pharmaceutical references "often include lists of synonyms because there are often a variety of terms used to describe compounds and classes of compounds," but that the synonyms are "not necessarily coterminous with the compound that is the subject of the entry, and they are often not coterminous." (D.I. 44-

[6] I will not grant Defendants' request to strike the untimely declaration of Dr. Byrn (D.I. 39 at p. 58 n.33), because Defendants had a full and fair opportunity to respond in their Sur-Reply.

15 at 13–14, ¶ 34). He thus opined that a POSITA would not view an entry for povidone as providing a definition for all of the listed synonyms. (*Id.*).

I do not think it necessarily follows that the definition of Term A accurately defines Term B simply because Term B is listed as a synonym of Term A, especially in a technical field like pharmaceutical formulation. *Cf. Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1374 (Fed. Cir. 2004) (holding that the district court erred in adopting the definition of a claim term's synonym instead of "the word that the inventor actually chose"). Defendants' route to defining polyvinylpyrrolidone is quite circular: they essentially limit the term to mean only povidone, by finding a definition of povidone (rather than of the claim term), and noting that the claim term is a synonym of povidone. This seems a less than exacting route to providing a correct definition. Accordingly, I find that these two intrinsic references do not define polyvinylpyrrolidone, and therefore do not provide the ordinary and customary meaning of the term.

The remainder of the specification does not provide clear guidance as to the meaning of the term. There is certainly nothing lexicographic in the specification or that otherwise demonstrates an intent on the part of the patentee to disavow or limit the term from its ordinary and customary meaning.[7] The term polyvinylpyrrolidone is used without any modifiers

[7] Defendants present two arguments that the '007 patent specification is inconsistent with the use of crospovidone. First, Defendants argue that claim 1's description of "the tampered tablet [being] dissolved in about 1 ml to about 5 ml of an aqueous liquid" requires that the excipient be dissolved and therefore necessarily excludes crospovidone, because it is undisputed that crospovidone is insoluble. (D.I. 39 at p. 30 (quoting '007 patent, claim 1)). Plaintiffs argue that, read in light of the specification, this claim language only requires the active ingredient to be dissolved, not necessarily the excipient. (*Id.* at pp. 56–57). I agree with Plaintiffs. The claim language refers to the tampered tablet being dissolved, not the excipient specifically. ('007 patent claim 1). The specification as a whole discusses a focus on the dissolution of the active ingredient. (*See, e.g., id.* col. 4, ll. 13–15 (discussing "liberat[ing] the opioid agonist" and "mak[ing] the opioid agonist available for inappropriate use")). Most significantly, Defendants' expert, Dr. Arthur Kibbe, admitted that the active ingredient can be dissolved, even if there are insoluble excipients. (D.I. 41-22, Tr. p. 86 ("[A]ll of these active ingredients in the opioid class of analgesics are normally highly water soluble. And so if there are excipients in the tablet which don't dissolve, you just simply filter them out. And then you take the liquid which contains the active ingredient and you inject it.")). Accordingly, I reject Defendants' argument that crospovidone, as an insoluble excipient, is inconsistent with the '007 patent.

Second, Defendants argue that the '007 patent characterizes polyvinylpyrrolidone as having a certain viscosity-average molecular weight, which is inconsistent with crospovidone, which can have no measurable molecular weight.

throughout the specification, where it is contemplated serving as a gelling agent, a disintegrant, or a binder in the context of the patented invention. ('007 patent, col. 6, ll. 36–49; *id.* col. 24, l. 32; *id.* col. 25, ll. 6–13). The specific examples of exact pharmaceutical formulations in the specification, however, use povidone as an ingredient, but never crospovidone. (*Id.* col. 30, ll. 10–25, ll. 55–65; *id.* col. 32, ll. 45–55; *id.* col. 35, ll. 5–20). Yet polyvinylpyrrolidone is the claim term the patentee chose, not povidone. I think that to limit this term to the ingredient described in specific examples would be to improperly import limitations from the specification into the claims, in contravention of clear Federal Circuit precedent. *See, e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc). In fact, I think the use of the term polyvinylpyrrolidone throughout the claims and specification, compared to the use of the specific ingredient povidone in the examples, suggests that polyvinylpyrrolidone is something broader than just povidone.

In the absence of a lexicographic definition or disavowal of the full scope of the claim term, the ordinary and customary meaning of polyvinylpyrrolidone must control. The intrinsic record, however, does not provide an unambiguous meaning of the claim term, aside from the general sense that it is broader than just povidone. It thus seems to be a particularly appropriate scenario to look to extrinsic evidence to determine the ordinary and customary meaning of the term, because polyvinylpyrrolidone is a "technical word[] . . . not commonly understood," and "extrinsic evidence may help to establish a usage of trade . . . ." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citation and internal quotation marks omitted).

(D.I. 39 at pp. 31–32 (citing '007 patent, col. 25, ll. 6–13)). Plaintiffs point out, however, that the specification does not require a particular range of molecular weights, but such molecular weights are only described in an example. (*Id.* at p. 56 (citing '007 patent, col. 25, ll. 4–20)). Plaintiff is correct: "An example of a binder includes, but is not limited to a therapeutically acceptable vinyl polymer having a 5,000 to 350,000 viscosity-average molecular weight . . . ." ('007 patent, col. 25, ll. 7–10). This exemplary discussion of a binder is not a disavowal of the full scope of the claim term and I decline to import this limitation into the claim. Accordingly, I find both of Defendants' arguments that the specification is inconsistent with crospovidone to be unpersuasive.

I think the extrinsic evidence makes clear that, as of the asserted August 6, 2001 priority date, a POSITA would have understood crospovidone as being a form of polyvinylpyrrolidone, and therefore encompassed by the claim term. A 1996 reference, ANALYTICAL PROFILES OF DRUG SUBSTANCES AND EXCIPIENTS, explains, "Crospovidone is the insoluble form of polyvinylpyrrolidone, and its use in the pharmaceutical industry as a tablet excipient (tablet disintegrant and tablet binder) has been widely documented."[8] (D.I. 40-21 at 7). The 2000 version of THE UNITED STATES PHARMACOPEIA defines crospovidone as "a water-insoluble synthetic cross-linked homopolymer[9] of N-vinyl-2-pyrrolidinone." (D.I. 40-33 at 4). It likewise defines povidone as "a synthetic polymer consisting essentially of linear 1-vinyl-2-pyrrolidinone groups, the degree of polymerization of which results in polymers of various molecular weights." (*Id.* at 7). A 1998 BASF publication, titled KOLLIDON:[10] POLYVINYLPYRROLIDONE FOR THE PHARMACEUTICAL INDUSTRY, explains that both soluble polyvinylpyrrolidone (povidone) and insoluble polyvinylpyrrolidone (crospovidone) are products of the polymerization of N-vinylpyrrolidone. (D.I. 40-30 at 10, 12). The BASF publication contains entirely separate chapters for both povidone and crospovidone. (*Id.* at 6). It repeatedly refers to povidone as "soluble polyvinylpyrrolidone" or "soluble Kollidon grades," and to crospovidone as "insoluble polyvinylpyrrolidone" or "insoluble Kollidon grades." (*See, e.g., id.* at 10, 12, 16, 130). Indeed, the very fact that there is an entire chapter covering crospovidone in a publication titled POLYVINYLPYRROLIDONE FOR THE PHARMACEUTICAL INDUSTRY strongly suggests that

[8] The specification discloses polyvinylpyrrolidone serving as a gelling agent, a disintegrant, or a binder. ('007 patent, col. 6, ll. 37–49; *id.* col. 24, ll. 31–32; *id.* col. 25, ll. 6–13). The fact that crospovidone's use in the pharmaceutical industry as a disintegrant and binder—purposes disclosed in the patent—was widely known as of 1996 indicates that the inclusion of crospovidone within the claim term is entirely consistent with polyvinylpyrrolidone's function in the patent.

[9] Defendants' expert, Dr. Kibbe, explains that a homopolymer is simply a term for a polymer that contains only one type of monomer. (D.I. 41-22, Tr. pp. 86–87). Dr. Kibbe indicated that both povidone and crospovidone are homopolymers of the same source monomer. (*Id.* at Tr. pp. 87–88).

[10] Kollidon is the brand name of BASF's polyvinylpyrrolidone products.

crospovidone is encompassed by the term polyvinylpyrrolidone.[11] A shared "unique, unmistakable identifier," like an identical CAS Registry number, also seems to ratify the notion that povidone and crospovidone fall under one common heading: polyvinylpyrrolidone. (D.I. 40-33 at 4, 6; D.I. 40-32 at 2).

Finally, I do not agree with Defendants' argument that, because references to polyvinylpyrrolidone specifically meaning crospovidone are always preceded by modifiers such as "cross-linked" or "insoluble," a reference to polyvinylpyrrolidone without modifiers does not include crospovidone. In certain publications, references to povidone are preceded by the modifier "soluble." (*See, e.g.*, D.I. 40-30 at 10, 16). If anything, I think describing crospovidone as "insoluble polyvinylpyrrolidone" confirms that it is indeed a form of polyvinylpyrrolidone, albeit with different structural properties. Nothing in the intrinsic record, however, purports to limit polyvinylpyrrolidone to the specific structural properties of povidone.[12] Thus, the ordinary and customary meaning of the term must control.

Accordingly, I construe the term "polyvinylpyrrolidone" to mean "a polymer of N-vinyl-2-pyrrolidone."

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion suitable for submission to the jury.

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[11] These technical references—dated 1996, 2000, and 1998 respectively—are timelier, with respect to the August 6, 2001 priority date, than Defendants' 1980 and 1986 references. These references also rebut Defendants' arguments that Plaintiffs are relying solely on references about general polymer chemistry without reference to the pharmaceutical industry, as the BASF publication and ANALYTICAL PROFILES come from the pharmaceutical field. In any event, I do not think a POSITA would look at the claim term in a manner entirely divorced from considerations of polymer chemistry.

[12] Had the patentee intended to limit the claim term to simply povidone, it could have done so by claiming soluble polyvinylpyrrolidone. Likewise, had the patentee wanted to limit the claim term to crospovidone, it could have could have done so unambiguously by claiming insoluble polyvinypyrrolidone or cross-linked polyvinylpyrrolidone. Yet the patentee chose the general term polyvinylpyrrolidone, and neither the ordinary and customary meaning of that term nor the specification provide a justification for limiting it to povidone.